IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

	:	**MDL DOCKET NO. 4:03-CV-1507-WRW**
IN RE:	:	
PREMPRO PRODUCTS LIABILITY	:	
LITIGATION	:	**ALL CASES**

ORDER DENYING PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

Pending is Plaintiffs' Motion for Class Certification (Doc. No. 80). Defendants have responded (Doc. No. 630). A Class Certification Hearing was held June 1-3, 2005. After the hearing, I sent a letter posing several questions. The parties responded with briefs, and another hearing was held on June 24, 2005. For the reasons set forth below, Plaintiffs' Motion for Class Certification is denied.

I. BACKGROUND

Wyeth and Wyeth Pharmaceuticals ("Wyeth") are Delaware corporations with principal places of business in New Jersey and Pennsylvania, respectively. Wyeth manufactures and distributes pharmaceuticals, including the prescription drugs Prempro, Premarin, Premphase, and Cycrin.

A. Premarin and Prempro

Premarin is an unopposed conjugated[1] estrogen prescription drug, which has been approved by the Food and Drug Administration ("FDA") for the treatment of moderate to severe

[1]Unopposed estrogen replacement therapy refers to the use of estrogen alone -- which means it is not combined with progestins. Conjugated estrogens are mixtures of several forms of estrogen that come from the urine of pregnant mares.

vasomotor symptoms -- such as hot flashes and night sweats -- associated with menopause; it has also been approved for the prevention of postmenopausal osteoporosis and the treatment of vaginal dryness.[2] Before Prempro, physicians often prescribed estrogen -- such as Premarin -- in combination with progestin to treat symptoms of menopause. All of this is commonly known as hormone replacement therapy ("HRT"). In 1994, the FDA approved the marketing of Prempro as separate tablets of Premarin and Cycrin,[3] blister packaged together so they could be taken at the same time. The FDA authorized Prempro for post-menopausal women with uteri for the treatment of vasomotor symptoms associated with menopause, including hot flashes, night sweats, and vaginal atrophy.[4] In 1995, the FDA approved the marketing of Prempro as a single tablet.[5]

Plaintiffs allege that, for decades, Wyeth has used general advertising, "direct-to-consumer" advertising, and other marketing tools to "orchestrate widespread misunderstanding among the general public and the medical community" on the benefits and risks of HRT.[6] According to Plaintiffs, Wyeth also promoted Prempro and HRT for off-label uses, i.e., uses not approved by the FDA.[7]

---

[2]Doc. Nos. 81 and 448.

[3]Cycrin is a medroxyprogeterone acetate ("MPA").

[4]Doc. Nos. 81 and 448.

[5]*Id.*

[6]Doc. No. 81, ¶¶ 26-33, 37-42.

[7]Doc. No. 81, ¶ 36.

B. Women's Health Initiative ("WHI")

The WHI is a long-term national health study focused on "defining the risks and benefits of strategies that could potentially reduce the incidence of heart disease, breast and colorectal cancer, and fractures in postmenopausal women."[8] The WHI Clinical Trial and Observational Study began in 1993 and has involved over 161,000 postmenopausal women.[9]

The estrogen plus progestin part of the WHI study involved 16,608 women ages 50-79 who had not had hysterectomies. Prempro was the only estrogen/progestin combination drug tested in this initial study. The study's objective was to examine the effectiveness of estrogen and progestin in heart disease and hip fracture prevention; and to examine any association between Prempro and the risks of breast and colon cancer.[10]

On May 31, 2002, the independent data and safety monitoring board ("DSMD") "concluded that the evidence for breast cancer harm, along with evidence for some increase in coronary heart disease, stroke, and pulmonary embolism, outweighed the evidence of a benefit for fracture and possible benefit for colon cancer,"[11] and recommended stopping the estrogen plus progestin component of the WHI trial early. On July 9, 2002, the National Heart, Lung and Blood Institute ("NHLB"), a division of the National Institutes of Health ("NIH"), stopped its major clinical trial for Prempro early. Plaintiffs allege that the study was stopped because "its evidence proved the drug dangerously increased women's risk of invasive breast cancer,

---

[8]Doc. No. 81, Ex. A.

[9]*Id.*

[10]Doc. Nos. 81 and 448.

[11]Doc. No. 81, Ex. A.

cardiovascular disease, stroke, venous thromboembolism, and pulmonary embolism . . . [and] Alzheimer's disease and dementia."[12]

The findings from the estrogen plus progestin component of the trial were published in the Journal of the American Medical Association ("JAMA") on July 17, 2002.[13] The article stated that, in the estrogen plus progestin component of the study, the "[o]verall health risks exceeded benefits from use of combined estrogen plus progestin for an average 5.2 year follow-up among healthy postmenopausal U.S. women."[14] In May 2003 an article appeared in JAMA that analyzed the incidence of dementia and mild cognitive impairment in the HRT component of the WHI study.[15] The article concluded:

> Estrogen plus progestin therapy increased the risk for probable dementia in postmenopausal women aged 65 years or older. In addition, estrogen plus progestin therapy did not prevent mild cognitive impairment in these women. These findings, coupled with previously reported WHI data, support the conclusion that the risk of estrogen plus progestin outweigh the benefits.[16]

Over the next couple of months, several other articles were printed in various medical journals involving analyses of the WHI study results.[17]

---

[12]Doc. No. 81.

[13]*See* J. Rossouw, et. al, *Risk and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women*, 288 JAMA 321 (July 17, 2002).

[14]Doc. No. 81, Ex. A.

[15]*See* Sally A. Shumaker, et. al, *Estrogen Plus Progestin and the Incidence of Dementia and Mild Cognitive Impairment in Postmenopausal Women*, 289 JAMA 2651 (May 28, 2003).

[16]Doc. No. 645, Ex. 2.

[17]*See* J. Hayes, et. al, *Effects of Estrogen plus Progestin on Health-Related Quality of Life*, 348 N. Engl. J. Med, 1839 (May 8, 2003); Rowan T. Chlebowski, et. al, *Influence of Estrogen plus Progestin on Breast Cancer and Mammography in Healthy Postmenopausal Women*, 289 JAMA 3243 (June 25, 2003).

II. ALLEGATIONS

Plaintiffs assert that they have been "significantly exposed to proven hazardous substances through the intentional, negligent, or wrongful actions" of Wyeth.[18] They state:

> As a direct and proximate result of Defendant's manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising, warning, and otherwise distributing Prempro in interstate commerce, Plaintiffs and class members are at a significantly increased risk of developing serious latent diseases and conditions including, *inter alia*, breast cancer, strokes, heart attacks, ovarian cancer, Alzheimer's disease, dementia, and blood clots.
>
> That increased risk makes periodic diagnostic medical examinations reasonably necessary. Medical surveillance, monitoring and testing procedures exist which make the early detection and treatment of disease possible and beneficial.
>
> Wyeth's actions render it liable to pay all costs of medical monitoring in the form of a comprehensive court-supervised medical monitoring program, to provide diagnostic and treatment services for the benefit of the class.[19]

Plaintiffs argue that class certification is appropriate here and propose two classes: (1) a consumer protection class under Federal Rule of Civil Procedure ("FRCP") 23(b)(3), which will include consumer fraud and unfair competition subclasses, and (2) a medical monitoring class under FRCP 23(b)(2), which will have breast cancer and dementia subclasses.[20]

Plaintiffs bottom their claims upon two facts they consider salient: (1) Wyeth falsely advertised and marketed HRT and Prempro; and (2) women face significantly increased risk of serious disease because they took Prempro.[21]

---

[18]Doc. No. 81.

[19]*Id.*

[20]Doc. No. 601.

[21]Doc. No. 601.

A. Consumer Protection Class

1. Consumer Fraud

Seeking relief under FRCP 23(b)(3), Plaintiffs include in their consumer fraud subclass:

> All women within Alabama, Alaska, Arkansas, California, Colorado, Delaware, Georgia, Idaho, Indiana, Kansas, Maryland, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, West Virginia, and Wyoming respectively, who purchased the prescription medication Prempro between its introduction in 1994 and July 2002.[22]

Plaintiffs allege: that Wyeth, through its direct to consumer advertisements, "falsely represented health benefits of [Prempro] and did not provide and deceptively concealed both the seriousness and the likelihood of known adverse reactions";[23] that Wyeth, grossly exaggerated the beneficial characteristics, uses, and benefits of Prempro; that Wyeth commenced a marketing campaign which contended that Prempro (1) would reduce the risk of heart disease, stroke, Alzheimer's disease, dementia, and depression; (2) would improve a consumer's mental acuity, help with incontinence, reduce wrinkles, and provide a "youthful glow"; and (3) was safe and approved for long-term use; that all of these benefits were unfounded; and that, at the same time that Wyeth embellished the benefits of Prempro, it simultaneously "concealed, obscured, and trivialized" the fact that Prempro increased the risks of breast cancer, stroke, heart attack, cardiovascular disease, Alzheimer's disease, dementia, and venous thromboembolism."[24]

---

[22] *Id.*

[23] Doc. No. 81.

[24] *Id.*

Plaintiffs submit that, as a result of Wyeth's actions, they have "suffered injuries in fact, ascertainable loss, and compensable damages," and are entitled to "equitable relief, including restitution of all monies paid for Prempro" and the creation of a medical monitoring program.[25] Plaintiffs further allege that they are entitled to "actual damages, disgorgement of Wyeth's profits accrued from their unfair, fraudulent, and unlawful practices, attorney's fees and costs," and punitive damages.

Plaintiffs claim that Wyeth's conduct constituted consumer fraud in violation of numerous state statutes.[26]

2. Unfair Competition

Seeking relief under FRCP 23(b)(3), Plaintiffs include in their unfair competition subclass:

> All women within Arizona, Arkansas, California, Connecticut, Delaware, Hawaii, Idaho, Illinois, Kentucky, Louisiana, Maine, Massachusetts, Minnesota, Missouri, Montana, Nebraska, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Washington, and Wisconsin respectively, who purchased the prescription medication Prempro between its introduction in 1994 and July 2002.[27]

For their unfair competition claim, Plaintiffs reassert the facts asserted in their consumer fraud claim, and add that "Wyeth derived profits and material gains as a direct and proximate

---

[25]*Id.*

[26]Plaintiffs list the relevant statutes of thirty two (32) jurisdictions (three of which are not included in their definition of the consumer fraud subclass -- namely, D.C., Illinois, and Pennsylvania). Doc. No. 81, ¶ 88.

[27]Doc. No. 601. Although Iowa was listed in the original Complaint as a state to be included in the subclass, it was removed in an Order granting partial dismissal (Doc. No. 295).

result of [its] unlawful, deceptive, and fraudulent representations."[28] They allege Wyeth, as a result of its conduct, continues to be "unjustly enriched in profits, income, and ill-gotten gains at the expense of the plaintiffs and the general public who purchased and consumed Prempro in reliance upon Wyeth's false, deceptive, and fraudulent business practices."[29]

Plaintiffs claim that Wyeth's unfair competition violated numerous state statutes.[30] They seek the same relief as in their consumer fraud claim, with the addition of actual damages where permitted by statute.

B. Medical Monitoring Class

Plaintiffs propose a medical monitoring class that will consist of two subclasses, which are defined below. Plaintiffs assert that their "increased susceptibility to injuries and [the] irreparable threat" to their health resulting from taking Prempro entitles them to the "creation of a court-supervised medical monitoring trust fund" that will finance a medical monitoring program for:

> . . . Locating persons who have used Prempro and notifying them of the potential harm from such use;
>
> . . . Aiding in the early diagnosis and treatment of resulting injuries through ongoing testing and monitoring of Prempro users;
>
> . . . Funding the design and implementation of further studies of the effects of Prempro on its users, including population-based studies of and for the

---

[28]Doc. No. 81.

[29]*Id.*

[30]Plaintiffs list the relevant statutes of thirty (30) states (two of which are not included in their definition of the unfair competition subclass -- namely, Florida and Iowa). Doc. No. 81, ¶ 105.

benefit of the Class, including the establishment of an adverse health effects registry;

. . . Funding research into possible cures for the detrimental effects of using Prempro; and,

. . . Gathering and forwarding to treating physicians information related to the diagnosis and treatment of injuries that may result from using Prempro.[31]

Plaintiffs assert that "Prempro exposure justifies medical monitoring because of its toxicity, the seriousness of the conditions Prempro causes, and the relative risk of developing the conditions."[32]

1. Breast Cancer Monitoring

Seeking relief under FRCP 23(b)(2), Plaintiffs include in their breast cancer medical monitoring subclass:

> All women within Arizona, Arkansas, California, Colorado, Connecticut, Florida, Illinois, Indiana, Kansas, Maryland, Michigan, Missouri, Nevada, New Jersey, New York, Ohio, Pennsylvania, Puerto Rico, Tennessee, Texas, Utah, Vermont, West Virginia, and Wyoming who used the prescription medication Prempro for at least 24 consecutive months until July 2002 and who are at increased risk of developing breast cancer (because of such exposure).[33]

Plaintiffs suggest that breast cancer medical monitoring will consist of four parts: (1) an initial screening questionnaire; (2) counseling to discuss the risks and benefits of Prempro and screening interventions; (3) MRIs in consenting women; and (4) additional studies, such as

[31]Doc. No. 81.

[32]Doc. No. 223.

[33]Doc. No. 601.

repeat mammography, echographic studies, or biopsies in women with suspicious lesions on their MRIs.[34]

2. Dementia Monitoring

Seeking relief under FRCP 23(b)(2), Plaintiffs include in their dementia medical monitoring, subclass:

> All women within Arizona, Arkansas, California, Colorado, Connecticut, Florida, Illinois, Indiana, Kansas, Maryland, Michigan, Missouri, Nevada, New Jersey, New York, Ohio, Pennsylvania, Puerto Rico, Tennessee, Texas, Utah, Vermont, West Virginia, and Wyoming who used the prescription medication Prempro for at least 24 consecutive months until July 2002 and who are at increased risk of developing dementia (because of such exposure).[35]

Plaintiffs' medical monitoring of dementia would include screening and counseling regarding dementia risks associated with Prempro. In addition to initial screening and counseling regarding Alzheimer's disease and dementia risks associated with the use of Prempro, Phase I would include testing that would annually use the Functional Activities Questionnaire ("FAQ") and the Modified Mini-Mental Status Examination ("MMMSE").[36] Phase II would involve more testing, including an annual Neuropsychiatric Exam and a Physical Exam for patients who scored below the Phase I cut-off. Plaintiffs assert that this testing will allow physicians to discover symptoms of dementia at an early stage.[37] If a patient has dementia symptoms, she will

---

[34]Doc. No. 687.

[35]Doc. No. 601.

[36]Doc. No. 687.

[37]*Id.*

participate in Phase III, which would provide information "concerning risks and benefits of further testing, preventative treatments, and other lifestyle changes."[38]

C. Other Causes of Action

Plaintiffs seek medical monitoring relief and disgorgement of Wyeth's profits[39] under the following causes of action:[40] (1) unjust enrichment, (2) negligence, (3) negligence per se, (4) strict liability -- failure to warn, and (5) negligent misrepresentation.

III. STANDING

Before addressing class certification issues, a court must determine whether the plaintiffs have standing to bring their suit.[41] Since a court must assume the truth of the facts alleged by the plaintiff at the class certification stage, the standard of review for standing is similar to the standard used to analyze a 12(b)(6) motion to dismiss.[42]

To establish standing: (1) the plaintiff must have "suffered an injury in fact"; (2) "there must be a causal connection between the injury and the conduct complained of"; and (3) "it must be likely . . . that the injury will be redressed by a favorable decision."[43]

---

[38]*Id*.

[39]Disgorgement of profits is requested as relief for only Count 3, Unjust Enrichment.

[40]During the June 24, 2004 status conference, Plaintiffs conceded that they were no longer seeking recovery of "moneys spent on Prempro" under these counts. *See* Doc. No. 295.

[41]*See Bertulli v. Independent Association fo Cont'l Pilots*, 242 F.3d 290, 294 (5th Cir. 2001) ("Standing is an inherent prerequisite to the class certification inquiry.").

[42]*In re Propulsid Products Liability Litigation*, 208 F.R.D. 133, 139 (E.D. La. 2002).

[43]*Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992).

As to injury-in-fact, Plaintiffs allege that their consumption of Prempro increased their risk of developing serious latent diseases and conditions including breast cancer, strokes, heart attacks, ovarian cancer, Alzheimer's disease, dementia, and blood clots. Plaintiffs satisfy the injury-in-fact element since courts have repeatedly agreed that an increased risk of harm is an injury-in-fact.[44]

The causation element is satisfied "when the injury alleged is fairly traceable to the challenged action of the defendant."[45] Here, Plaintiffs assert that the increased risks of certain latent diseases and conditions are attributable to a drug manufactured by Defendant, and that this injury can be traced to Defendant because of Defendant's failure to test adequately and sufficiently warn of the dangers of the drug. Accordingly, Plaintiffs have met their burden of establishing (for the purpose of standing) that the alleged injury is fairly traceable to Defendant's alleged wrongful acts.

Finally, Plaintiffs must establish that the injury can be "redressed" by a favorable court decision. Plaintiffs ask for the creation of a medical monitoring program and disgorgement of Wyeth's profits; this would redress the alleged injuries suffered by Plaintiffs.

Accepting as true the facts asserted by Plaintiffs, as I must at this stage of the litigation, Plaintiffs have established injury-in-fact, causal connection, and redressability. Accordingly, Plaintiffs have Article III standing.

---

[44]*In re Propulsid*, 208 F.R.D. at 139; *See also Friends For All Children, Inc. v. Lockheed Aircraft Corp*., 746 F.2d 816 (D.C. Cir. 1984); *In re Paoli R.R. Yard PCB Litigation*, 916 F.2d 829 (3d Cir. 1990); *In re Orthopedic Bone Screw Products Liability Litigation*, 1999 WL 455667 (E.D. Pa. July 2, 1999).

[45]*In re Propulsid*, 208 F.R.D. at 139.

IV. CHOICE-OF-LAW

In cases where the plaintiffs, pursuing common law claims, request the certification of a class that involves multi-state parties, courts must address choice-of-law issues.[46] Unlike a federal question case (where the diversity of the parties does not matter), when class certification is sought in a case based on common law claims, the question of which law governs is crucial in making a class certification determination. Not only must the choice-of-law issue be addressed at the class certification stage -- it must be tackled at the front end since it pervades every element of FRCP 23.

FRCP 23 makes no reference to choice-of-law issues, but, in nationwide class actions, choice-of-law constraints are constitutionally mandated because a party has a right to have her claims governed by the state law applicable to her particular case.[47] Therefore, choice-of-law issues may be present in any number of FRCP 23's subsections[48] -- and they are pervasive in this case. So, as indicated above, identifying the state substantive laws that may control the outcome of the litigation is a threshold matter when making findings regarding class certification.

---

[46]*In re Jackson Nat. Life Ins. Co. Premium Litigation*, 183 F.R.D. 217, 223 (W.D. Mich. 1998) (citing *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 821-23 (1985)).

[47]*In re Ford Motor Co. Ignition Switch Products Liability Litigation*, 174 F.R.D. 332, 347-48 (D.N.J. 1997) (citing *Phillips Petroleum Co. v. Shutts*, 472 U.S. at 821-23).

[48]*See Castano v. American Tobacco Co.*, 84 F.3d 734, 741 (5th Cir. 1996) ("A requirement that a court know which law will apply before making a predominance determination is especially important when there may be differences in state law."); *In re Baycol Products Litigation*, 218 F.R.D. 197, 207, 211-12 (D. Minn. 2003) (addressing the choice-of-law issue as it pertains to Rule 23(b)(3), and pointing out the how the differences in state law preclude the formation of a medical monitoring class under 23(b)(2)); *In re Propulsid*, 208 F.R.D. at 145 (addressing the choice-of-law as its own factor, and then applying it to the proposed 23(b)(2) class); *In re Paxil Litigation*, 212 F.R.D. 539, 544-45 (C.D. Cal. 2003) (holding that choice-of-law issues prevented a manageable class under Rule 23(a)).

Typically courts perform a choice-of-law analysis when assessing the predominance requirement[49] of Rule 23(b)(3).[50] However, in cases like these -- where multi-state plaintiffs pursue common law causes of action under both 23(b)(2) and (b)(3) -- the choice-of-law determination affects every aspect of class certification. Plaintiffs' common law claims are not insulated from the choice-of-law analysis simply because they are grouped under 23(b)(2). Accordingly, Plaintiffs must show, "prior to class certification, that the differences in state laws within each of their groupings are nonmaterial"[51] as to both their 23(b)(3) *and* 23(b)(2) classes.

A. Plaintiffs' Response to Choice-of-law

In an effort to overcome the choice-of-law problems, Plaintiffs contend that: (1) this is not a nationwide class action; (2) their proposed subclasses properly group states with quite similar laws; and (3) jury instructions can be tailor-made to properly inform a jury of the substantive law.

1. Not a Nationwide Class

As noted above, Plaintiffs claim that their case is not a nationwide class action.[52] The proposed subclasses include women from 29 states (consumer fraud), 28 states (unfair competition), and 24 states (medical monitoring), which means the proposed subclasses face the

---

[49]FED. R. CIV. P. 23(b)(3) requires the court to find that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members.

[50]*Spence v. Glock, Ges.m.b.H.*, 227 F.3d 308, 311 (5th Cir. 2000) (holding that a "predominance finding depends on [a court's] choice of law analysis"); *see also Castano*, 84 F.3d at 741.

[51]*In re Paxil*, 212 F.R.D. at 545.

[52]Doc. No. 669.

same choice-of-law problems that a nationwide class would face. Plaintiffs concede that the state law for each state identified in each subclass will govern.[53] This means that certifying any of Plaintiffs' claims would require applying the law of at least 24 states. Plaintiffs must show that class certification is appropriate when the proposed classes involve the laws of 24-29 different states.

While this case may not be a nationwide class (it doesn't include 50 states), it involves many states, and Plaintiffs failed to submit either a trial plan or jury instructions effectively demonstrating that this case could be managed as a class action, considering the laws of numerous states.

2. Proposed Trial Plan / Grouping/ Jury Instructions

To meet their burden of providing an "extensive analysis" of state law variations, and establishing that there are not "insuperable obstacles" to class certification, the plaintiffs must provide the court with "model jury instructions and verdict forms, as well as . . . [a grouping] of state laws by their relevant differences."[54] Plaintiffs have made a run at this, but their proposals do not show that certification is appropriate in light of the differences in state law.

Plaintiffs assert that their proposed subclasses resolve any potential choice-of-law issues.[55] Additionally, they contend that "[a]ny such differences in states' laws are not substantial

---

[53]*Id.*

[54]*In re Rezulin Products Liability Litigation*, 210 F.R.D. 61, 71 n.59 (S.D.N.Y. 2002).

[55]Plaintiffs assert that "the classes in this case as well as the claims at issue can be handled in an efficient manner so as to easily accommodate any differences in states' law." (Doc. No. 601); The proposed subclasses "have materially identical consumer protection and false advertising law." (Doc. No. 669).

enough to preclude class certification in this case,"[56] and "do not make the class unmanageable."[57] To the contrary, Plaintiffs' proposed groupings, jury instructions, and trial plan reflect complications that make any of the proposed subclasses ill-suited for class certification.

Plaintiffs further suggest that not only can these states be grouped, but -- in regard to instructing the jury -- the Court will be able to "come up with common instructions that provide for the base from which lesser-included offenses might be carved out."[58] In their Model Class Trial Plan, Plaintiffs argue that "the court will instruct the jury using jury charges for each subclass incorporating the material elements of law from the respective subclass jurisdiction."[59]

Plaintiffs' argument that the variations in state laws are not substantial is unduly sanguine. In an attempt to show that the laws are generally uniform, Plaintiffs have presented a listing of states' laws for consumer fraud, unfair competition, and unjust enrichment.[60] But, a study of this listing leads me to a conclusion contrary to the one urged by Plaintiffs.

In fact, a review of the unjust enrichment and consumer fraud/unfair competition claims reveals that these laws cannot reasonably be grouped in a comprehensive manner that does not seriously impinge on the integrity of the law of each state.

---

[56]Doc. No. 601.

[57]Doc. No. 669.

[58]June 24, 2005 Tr. at 11, lines 43-47.

[59]Doc. No. 686.

[60]Doc. No. 601, Exs. B, C, and D.

a. Unjust Enrichment

On this point, Plaintiffs argue that states' laws "form a common nucleus in that they prohibit, or otherwise provide a remedy, where a plaintiff has conferred a benefit on a defendant and it would be unjust or inequitable for defendant to retain that benefit."[61] However, this generalization fails to recognize the differences in state laws. As a matter of fact,

> [t]he actual definition of "unjust enrichment" varies from state to state. Some states do not specify the misconduct necessary to proceed, while others require that the misconduct include dishonesty or fraud . . . .Other states only allow a claim of unjust enrichment when no adequate legal remedy exists . . . . Many states, but not all, permit an equitable defense of unclean hands. Those states that permit a defense of unclean hands vary significantly in the requirements necessary to establish the defense . . . .[62]

Additionally, "some states consider unjust enrichment a remedy at law, while others consider it an equitable claim."[63] If this were not enough, Plaintiffs' jury instructions indicate numerous differences by creating seven "additional instructions" to supplement their main unjust enrichment instruction;[64] and these may not be sufficient to encompass all the important differences in the states' unjust enrichment laws.

b. Consumer Fraud / Unfair Competition

The problems mentioned above apply to Plaintiffs' consumer fraud and unfair competition claims as well. Plaintiffs assert that consumer fraud laws of the listed states "form a common nucleus in that they uniformly prohibit a Defendant from representing that goods have

---

[61]Doc. No. 601.

[62]*Clay v. American Tobacco Co.*, 188 F.R.D. 483, 501 (S.D. Ill. 1999).

[63]*In re Baycol*, 218 F.R.D. at 214 (citations omitted).

[64]Doc. No. 601, Ex. D.

approval, characteristics, uses, benefits or qualities that they do not have."[65] Regarding unfair competition, Plaintiffs claim that the law of the listed states "form a common nucleus in that all prohibit any business act or practice which is fraudulent or deceptive."[66]

Plaintiffs oversimplify. Both consumer fraud and unfair competition laws of the states differ with regard to the defendant's state of mind,[67] type of prohibited conduct, proof of injury-in-fact, available remedies, and reliance, just to name a few differences. The *Rezulin* court noted that the plaintiffs' proposed consumer fraud class would require a court to "apply the laws of all fifty states to determine the need for proving such matters as intent, reliance, causation and injury before even addressing the form and extent of any relief that might be appropriate."[68]

A cursory review of the differences in reliance, scienter, and statute of limitations (and this is by no means a conclusive list of differences) reveals that Plaintiffs' proposed subclasses are quite imprecise. For example:

	Scienter	Reliance	Statute of Limitations	Statute of limitations runs from date of
Arkansas	Yes	No	5 yrs	transaction
California	No	No	3 yrs	transaction
Colorado	Yes	No	3 yrs	discovery
Georgia	No	Yes	2 yrs	discovery
Wyoming	Yes	Yes	1 yr	discovery

[65]Doc. No. 601.

[66]*Id.*

[67]States vary on whether the plaintiff must prove that the defendant acted willfully, knowingly, or intentionally. Some states do not require scienter.

[68]*In re Rezulin*, 210 F.R.D. at 68-69.

From this table it is clear that none of these states could properly be grouped together. A plaintiff from California could not be grouped with a Wyoming plaintiff because Wyoming requires proof of scienter and reliance; California could not be grouped with Arkansas either, because Arkansas requires scienter. While California squares with other states that require neither scienter nor reliance (e.g.. Alabama or Ohio), other issues -- e.g. statute of limitations, measure of damages -- would then come into play, preventing the grouping, as a practical matter.

Variations in state law plague the other common law claims that Plaintiffs do not specifically outline in their briefs -- e.g. failure to warn, negligence, negligent misrepresentation, and medical monitoring.[69]

The Seventh Circuit stated that "the voices of the quasi-sovereigns that are the states of the United States sing negligence with a different pitch."[70] The same can be said for common law claims generally. Plaintiffs' proposals establish this point. First, not a single, accurate, understandable jury instruction that addresses the differences in state law has been presented -- for any of Plaintiffs' claims. Apparently, the only way to encompass the various state common law in one instruction -- or a tight package of instructions -- is with the creation of an Esperanto[71]

---

[69]*See Block v. Abbott Laboratories*, 2002 WL 485364 (N.D. Ill. March, 29 2002) (failure-to-warn); *Matter of Rhone-Poulenc Rorer Inc.*, 51 F.3d 1293, 1300-01 (7th Cir. 1995) (negligence); *In re Paxil*, 212 F.R.D. at 544-45 (negligence); *McManus v. Fleetwood Enterprises, Inc.*, 320 F.3d 545, 549-50 (5th Cir. 2003) (negligent misrepresentation); *In re Rezulin*, 210 F.R.D at 75 (medical monitoring); *In re Baycol*, 218 F.R.D. at 211 (medical monitoring).

[70]*Matter of Rhone-Poulenc Rorer Inc.*, 51 F.3d at 1301.

[71]Esperanto is an artificial language, created by Dr. L.L. Zamenhof in 1887, which combines word roots common to many European languages. It was designed to help with the communication between people of different lands and cultures, and was meant to be a second language.

instruction -- a "solution" that has been expressly rejected.[72] Second, Plaintiffs have not presented a manageable listing of subclasses that encompasses the laws of the various states. I cannot think of -- and apparently Plaintiffs could not either -- any way to subclass these states without creating a tangled web of plaintiffs and laws.

When asked about the subclasses and jury instructions at the certification hearing, Plaintiffs acknowledged that they may need to "kick this around a little bit more."[73] However, on the whole, they stood their ground stating that, just because this will be complex, "doesn't mean that it can't be done."[74] In the absence of a satisfactory showing that the variations in state laws can be reasonably reconciled with, at the very least, jury instructions capable of being understood by a jury, and a trial plan that adequately sets forth how the case will proceed, class certification is not warranted.[75]

When proposed classes "threaten to undermine whatever benefits class certification might otherwise provide . . . [a court] is 'not content merely to certify an action as a proper class suit and then suggest that all the problems raised by the parties may be adjusted or handled at a later

---

[72]*See Matter of Rhone-Poulenc Rorer Inc.*, 51 F.3d at 1301.

[73]June 2, 2005 Tr. at 346, line 12.

[74]June 2, 2005 Tr. at 347, lines 7-8.

[75]As an aside, the fact that the parties do not agree on which states require scienter is additional proof of the improbability of a workable trial plan that would adequately recognize the differences among state laws. For example, Plaintiffs claim that Alabama does not require scienter, but Defendants claim that scienter must meet the "knowingly" standard. Also, Plaintiffs claim that Delaware does not require scienter, but Defendants claim that a plaintiff must prove that a defendant intended to deceive the consumer. *See* Doc. Nos. 601, Ex. A and 668, Ex. 1.

stage.'"[76] While a multitude of subgroups might solve the variation of laws problem, it would lead to monumental case management problems. Plaintiffs must establish that the variances in state laws could be overcome in a reasonable way. They have failed to meet this burden.

Incidentally, I have carefully studied Judge Tunheim's thoughtful analysis in *In re St. Jude Medical, Inc. Silzone Heart Valves Products Liability Litigation.*[77] In fact, my study of the *St. Jude* case has caused some delay in the entry of this order. It is obvious that he has taken on a considerable task in certifying the class, which involves the laws of 17 states. In light of my view of class actions, I might well be inclined to follow his lead but, for the reasons stated above and below, the case before me has substantial additional complications. (I note parenthetically that the parties here designate the *St. Jude* case as a "medical device" case, and this case, as well as the "big four" cases[78], as "drug" cases.) Since the primary complaint in *St. Jude* regards the "Silzone heart valve, which has a coating of silver on the sewing cuff,"[79] I'm nowise certain that this distinction is apt. But this does not affect my decision in this case.

---

[76]*In re Paxil*, 212 F.R.D. at 545 (quoting 7A WRIGHT, MILLER & KANE, *FEDERAL PRACTICE & PROCEDURE* § 1754 (2d ed. 1986)).

[77]2003 WL 1589527 (D. Minn. March 27, 2003).

[78]This is the name Wyeth gave to *In re Baycol*, MDL-1431; *In re Rezulin*, MDL-1348; *In re Propulsid*, MDL-1355; *In re Paxil*, MDL-1574.

[79]*In St. Jude*, 2003 WL 1589527, at *1. The silver coating on the Silzone valve was introduced to combat endocarditis, so in a sense, *In re St. Jude* involved a hybrid medical device/drug claim.

V. CLASS CERTIFICATION STANDARD

Even if Plaintiffs could overcome the choice-of-law issues, their claims would fail to meet the requirements of FRCP 23.

To obtain class certification, Plaintiffs must meet all four requirements of Rule 23(a) and the requirements of at least one of the subdivisions of Rule 23(b).[80] A case is "not maintainable as a class action by virtue of its designation as such in the pleadings."[81] Instead, "[t]here must be an adequate statement of the basic facts to indicate that each requirement of the rule is fulfilled."[82] The party seeking class certification has the burden of establishing that certification is appropriate.[83]

A class should not be certified until the district court has found "through rigorous analysis, that all the prerequisites of Rule 23(a) have been satisfied."[84] A district court "has broad discretion in determining whether to certify a class."[85] However, some believe that a court should rule in favor of class certification in a close case, since it may amend an order granting class certification (this approach, however, can compound the problems).[86]

---

[80] FED. R. CIV. P. 23(b).

[81] *In re American Medical Sys., Inc.*, 75 F.3d 1069, 1079 (6th Cir. 1996).

[82] *Id.*

[83] *Id.*

[84] *General Telephone Co. of Southwest v. Falcon*, 457 U.S. 147, 161 (1979).

[85] *Gilbert v. City of Little Rock, Ark.*, 722 F.2d 1390, 1399 (8th Cir. 1983).

[86] *Barnes v. American Tobacco Co.*, 176 F.R.D. 479, 484 (E.D. Pa. 1997).

Here, Plaintiffs seek to certify one class (two subclasses) under FRCP 23(b)(3), and one class (two subclasses) under 23(b)(2). While Plaintiffs must satisfy the FRCP 23(a) requirements for each proposed class and subclass,[87] I will first address Plaintiffs' 23(b)(3) and (b)(2) claims.

A. FRCP 23(b)(3) Requirements

Plaintiffs seek to certify a consumer fraud subclass and an unfair competition subclass under FRCP 23(b)(3). For certification under FRCP 23(b)(3), Plaintiffs must establish, in addition to meeting the requirements of 23(a), that common questions of law or fact predominate, and that a class action is the superior method for fair and efficient adjudication of the controversy.[88] Determining whether common issues predominate and the class action is superior requires consideration of the relevant claims, defenses, facts, and substantive law presented.[89]

1. Predominance

While Rule 23(b)(3) parallels subdivision (a)(2), in that both require that common questions exist, subdivision (b)(3) contains the more stringent requirement that common issues "predominate" over individual issues.[90] "To satisfy the 'predominance' standard, plaintiffs must show that [their claims] can be proven on a systematic, class-wide basis."[91]

Plaintiffs contend that there are questions of law and fact common to all cases because "Wyeth engaged in a marketing campaign designed to increase HRT sales generally and Prempro

---

[87] *Paxton v. Union National Bank*, 688 F.2d 552, 559 (8th Cir. 1982).

[88] FED. R. CIV. P. 23(b)(3).

[89] *See Castano*, 84 F.3d at 744.

[90] *See In re American Medical Systems, Inc.*, 75 F.3d at 1084.

[91] *Blades v. Monsanto Co.*, 400 F.3d 562, 569 (8th Cir. 2005).

specifically," and this marketing campaign "consisted of falsehoods and deception that affected . . . every putative class member's use of Prempro."[92] They argue that "predominance is satisfied here, because when [Wyeth] acted to one [plaintiff], it acted to them all."[93] Defendants do not dispute that there are some common issues of fact and law, but contend that individual issues predominate.

a. Questions of Law do Not Predominate

As mentioned earlier, each plaintiff's case must be analyzed under the law of her[94] state. This means the consumer fraud laws of the 29 states and the unfair competition laws of 28 states must be followed. Again, Plaintiffs contend that these differences are minute.[95] However, "[i]n multi-state class actions, variations in state law may swamp any common issues and defeat predominance."[96] As is more fully explained above, the state-by-state variations in law trump the common issues of law or fact, and preclude a finding that common issues predominate.[97]

b. Questions of Fact do Not Predominate

Even if Plaintiffs could overcome the variations in state law, they cannot show that common questions of fact predominate.

---

[92]Doc. No. 601.

[93]June 2, 2005 Tr. at 288, lines 9-10.

[94]It is a relief to be able to use this gender based pronoun without thinking. This is because only women take these drugs -- at least as far as I know.

[95]Doc. No. 601.

[96]*See Castano*, 84 F.3d at 741.

[97]*In re American Medical Systems, Inc.*, 75 F.3d at 1085.

The United States Supreme Court cautioned:

> [i]n products liability actions . . . individual issues may outnumber common issues. No single happening or accident occurs to cause similar types of physical harm or property damage. No one set of operative facts establishes liability. No single proximate cause applies equally to each potential class member and each defendant. Furthermore, the alleged tortfeasor's affirmative defenses (such as failure to follow directions, assumption of the risk, contributory negligence, and the statute of limitations) may depend on facts peculiar to each plaintiff's case.[98]

Plaintiffs' causes of action "raise a host of individual issues."[99] For example, the consumer fraud claim "require[s] individualized proof concerning reliance and causation."[100] Whether a plaintiff saw an advertisement; whether the particular advertisement was fraudulent; whether that plaintiff relied on the advertisements; and whether the plaintiff was damaged as a result of the advertisement are all individual questions of fact.

Additionally, Defendants' potential liability will differ from class member to class member depending on when she took the drug. Because Wyeth's promotional material, informational literature, and advertising changed over time, what and when a plaintiff saw the advertisement will differ from plaintiff to plaintiff, directly affecting whether Wyeth violated any consumer fraud laws. And, since scientific knowledge is constantly changing, a 1995 ad making certain claims might not be fraudulent, however if made in 1999, it might well be.

Another consideration is affirmative defenses. While they do not automatically render class certification inappropriate, they must be considered when determining whether common

---

[98] *Georgine v. Amchem Products, Inc.*, 83 F.3d 610, 628 (1996).

[99] *In re Rezulin*, 210 F.R.D. at 66-67.

[100] *Id.* at 68.

issues predominate.[101] When affirmative defenses "'may depend on facts peculiar to each plaintiff's case,' class certification is erroneous."[102] Assumption of the risk, contributory negligence, comparative negligence, and statutes of limitation all require individual determinations.[103]

Finally, in the states that require it, the issue of reliance raises a multitude of individual issues. The *Paxil* court explained:

> because the putative plaintiffs all took Paxil at different times, some of those patients may have ingested Paxil and withdrawn from it before the advertisements at issue were aired or may have never seen the advertisements. With the information before it, the Court has significant doubts with respect to Plaintiffs' ability to show reliance, other than on a tedious case by case basis.[104]

Because reliance "must be applied with factual precision," Plaintiffs' fraud and unfair competition claims do not provide "a suitable basis for class-wide relief."[105]

As in many cases before them, Plaintiffs have attempted to frame the "predominant" issues broadly to compensate for variations in the class members' claims. But they suffer the

---

[101] *Gunnells v. Healthplan Services, Inc.*, 348 F.3d. 417, 438 (4th Cir. 2003).

[102] *Broussard v. Meineke Discount Muffler Shops, Inc.*, 155 F.3d 331 (4th Cir. 1998) (quoting *In re Northern Dist. of Cal. Dalkon Shield IUD Prods. Liab. Litig.*, 693 F.2d 847, 853 (9th Cir. 1982).

[103] *See Arch v. American Tobacco, Inc.*, 175 F.R.D. 469, 491 (E.D. Pa. 1997) ("Assumption of risk is an inherently individual question, turning as it does upon the subjective knowledge and behavior of individual plaintiffs."); *See also Guillory v. American Tobacco, Co.*, 2001 WL 290603, at *9 (N.D. Ill. March 20, 2001) (assumption of risk); *In re Ford Motor Co. Ignition Switch*, 194 F.R.D. at 490 (comparative and contributory negligence); *Barnes v. American Tobacco Co.*, 161 F.3d at 149 (statute of limitations).

[104] *In re Paxil*, 212 F.R.D. at 548.

[105] *Broussard*, 155 F.3d at 342.

same fate. "[I]ndividual issues abound and are magnified by the necessity of applying diverse state laws," making certification under 23(b)(3) inappropriate.[106]

2. Superiority

Plaintiffs have failed to show a predominance of common facts or law. They also have failed to meet their burden of establishing that a class action is the superior way to handle this litigation. Of course, the failure to show predominance spills over onto superiority. FRCP 23(b)(3) requires Plaintiffs to establish that "a class action is superior to other available methods for the fair and efficient adjudication of the controversy."[107] "[T]he purpose of the superiority requirement is to assure that the class action is the most efficient and effective means of settling the controversy . . . ."[108] "The difficulties likely to be encountered in the management of a class action" are strongly considered when analyzing superiority.[109]

Again, state law variation rears its head. It is well settled that the application of multiple state laws can render a case unmanageable.[110] Here, because the law varies in material ways from state to state and because individual factual determinations saturate Plaintiffs' common law claims, a class action trial is not the superior method for resolving these cases.[111]

---

[106]*Andrews v. American Tel. & Tel. Co.*, 95 F.3d 1014, 1025 (11th Cir. 1996).

[107]FED. R. CIV. P. 23(b)(3).

[108]7AA WRIGHT, MILLER & KANE, *FEDERAL PRACTICE & PROCEDURE* § 1779 (3d ed. 2005).

[109]FED. R. CIV. P. 23(b)(3)(D).

[110]*See, e.g., Andrews*, 95 F.3d at 1024-25; *Castano*, 84 F.3d at 741-44.

[111]*See, e.g., In re Bridgestone/Firestone, Inc.*, 288 F.3d 1012 (7th Cir. 2002) (denying nationwide class certification because variances in consumer protection and fraud laws rendered

Plaintiffs' failure to present a manageable plan supports the conclusion that the multi-state laws render this case unmanageable. The trial plan in this case has many of the same flaws as the one rejected in *In re Paxil*:

> The trial plan, which sketches the proposed plan of action in only the broadest strokes, is itself six pages. The description does not even begin to lay out the specific elements required to prove certain causes of actions. The completed picture will no doubt be too vast and too complicated for even the most diligent jury to grasp. Thus, any attempt to proceed with this trial plan is bound to result in trial management problems and jury confusion.[112]

Additionally, as discussed earlier, Plaintiffs failed to provide even one accurate, understandable jury instruction that sufficiently addressed the differences in state law. The absence of an adequate trial plan and proper jury instructions supports what Defendants have said all along -- there is no way that the claims of these multi-state plaintiffs can be adequately addressed in a single class action trial.

In fine, the presence of individualized determinations under a variety of state laws weighs against the superiority of a class action.[113] Since Plaintiffs have failed to demonstrate that this

---

class unmanageable); *Lyon v. Caterpillar, Inc*., 194 F.R.D. 206 (E.D. Pa. 2000) (rejecting nationwide certification, finding consumer fraud laws of the various states are not uniform and management problems are likely to arise from the need to determine and apply the various consumer fraud acts); *Szabo v. Bridgeport Mahines, Inc.*, 249 F.3d 672, 674 (7th Cir. 2001) (holding that a "nationwide class in what is fundamentally a breach-of-warranty action, coupled with a claim of fraud, poses serious problems about choice of law, the manageability of the suit, and thus the propriety of class certification").

[112]*In re Paxil*, 212 F.R.D. at 546.

[113]*See Schwartz v. Upper Deck, Co.*, 183 F.R.D. 672, 679 (S.D. Cal. 1999) ("When individualized determinations must be made, and then applied under the gamut of state law, class certification would provide massive manageability problems for a court."); *Lyon v. Caterpillar, Inc.*, 194 F.R.D. at 223 (finding class action not superior where "[m]anagement problems are likely to result from the need to determine and apply the various states' consumer fraud acts").

case would be manageable -- because of the differences in the facts of each case and differences in state laws -- they have not met the superiority requirement.

B. FRCP 23(b)(2) Requirements

Under FRCP 23(b)(2), a class action may be maintained where "the party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole."[114]

Plaintiffs propose a medical monitoring subclass under FRCP 23(b)(2).[115] They pursue both a cause of action for medical monitoring, and, under several common law causes of action, medical monitoring as a remedy. Plaintiffs assert that Wyeth marketed, promoted, and distributed Prempro nationally while simultaneously hiding the harmful effects of the drug; and falsely promoted and exaggerated the benefits of Prempro -- all in a way that generally applies to the class of Prempro users.[116] Plaintiffs assert that they are at an increased risk of serious disease because they took Prempro. On this basis, Plaintiffs, who are all asymptomatic, seek injunctive relief by way of a court-supervised medical monitoring program.

---

[114]FED. R. CIV. P. 23(b)(2).

[115]The proposed class will consist of a breast cancer medical monitoring subclass and a dementia medical monitoring subclass.

[116]This is the exact claim that is made in *In re Propulsid*, 208 F.R.D. 133 and *In re Baycol*, 218 F.R.D. 197.

While 23(b)(2) class actions do not have the predominance or superiority requirements of 23(b)(3), courts have held that the class claims under 23(b)(2) must be cohesive.[117] In fact, "a (b)(2) class should actually have more cohesiveness than a (b)(3) class."[118] A class cannot be cohesive if the states' laws governing the class are notably different. Nor can it be cohesive if the factual differences between the proposed class members would "translate into significant legal differences."[119]

First, as discussed earlier, the variation in state laws is at issue. States differ greatly on their approach to medical monitoring both as a cause of action and as a remedy. Plaintiffs' proposed medical monitoring subclasses include twenty four (24) states that indisputably address medical monitoring in a number of ways. For example, Arizona and New York allow stand-alone medical monitoring claims absent proof of injury;[120] Michigan, Missouri, and Nevada

---

[117]*See Barnes v. American Tobacco Co.*, 161 F.3d at 143 (holding that "[a]lthough a case may be certified under Rule 23(b)(2), which does not have a superiority or predominance requirement, certification under (b)(2) does not relieve a court of its obligation to determine whether the existence of individual issues preclude certification"); *See also In re Rezulin*, 210 F.R.D. at 75; *Thompson v. American Tobacco Co., Inc.*, 189 F.R.D. 544, 557 (D. Minn. 1999); *In re St. Jude Medical, Inc Silzone Heart Valves Products Liability Litigation*, 2003 WL 1589527, at *14 (D. Minn. March 27, 2003); *In re Baycol Products*, 218 F.R.D. at 211.

[118]*Barnes v. American Tobacco Co.*, 176 F.R.D. at 500. *See also Santiago v. City of Philadelphia*, 72 F.R.D. 619, 628 (D.C. Pa. 1976) (holding that a "court should be more hesitant in accepting a (b)(2) suit which contains significant individual issues than it would under subsection 23(b)(3)").

[119]*In re Baycol*, 218 F.R.D. at 211 (citing *Barnes v. American Tobacco Co.*, 161 F.3d at 143).

[120]*See Burns v. Jaquays Min. Corp.*, 752 P.2d 28, 33-34 (Ariz. Ct. App. 1987); *Patton v. General Signal Corp.*, 984 F. Supp. 666, 674 (W.D.N.Y. 1997).

allow stand-alone medical monitoring claims, but require proof of injury;[121] Arkansas has rejected medical monitoring as a cause of action, and questions its availability as a remedy;[122] California and Vermont permit medical monitoring as a damages claim only;[123] and Indiana, Maryland, and Puerto Rico have not addressed medical monitoring either as a cause of action or as relief. "The fact that medical monitoring is not treated uniformly throughout the United States creates a myriad of individual legal issues" that may swamp any possible cohesion in a 23(b)(2) class.[124]

Additionally, regardless of whether a medical monitoring claim is recognized as a separate cause of action, or as an element of damages, "state laws generally require a finding that a plaintiff's exposure to a toxic substance was due to defendant's negligence."[125] "[A] finding of negligence is inextricably intertwined with individual issues,"[126] which would undermine the

---

[121]*See Henry v. Dow Chemical Co.*, 2005 WL 1869555, at *3 (Mich. Jul. 13, 2005); *Thomas v. FAG Bearings Corp. Inc.*, 846 F. Supp. 1400, 1410 (W.D. Mo. 1994); *Badillo v. American Brands, Inc.*, 16 P.3 435 (Nev. 2001).

[122]*See Baker v. Wyeth-Ayerst Labs. Division*, 992 S.W.2d 797, 799 (Ark. 1999).

[123]*See Potter v. Firestone Tire & Rubber Co.*, 863 P.2d 795, 823 (Cal. 1993); *Stead v. F.E. Myers*, 785 F. Supp. 56, 57 (D. Vt. 1990).

[124]*Zehel-Miller v. Astrazenaca Pharmaceuticals, LP*, 223 F.R.D. 659, 663 (M.D. Fla. 2004).

[125]*In re Baycol*, 218 F.R.D. at 212.

[126]*Id.* at 211.

cohesion of the medical monitoring subclasses.[127] While this is not always the case, it is the case here.

A "myriad of individual issues" also exists for the other common law claims under which Plaintiffs request medical monitoring relief -- presumably to cover the states that do not recognize medical monitoring as an independent cause of action. As was discussed earlier, Plaintiffs' common law claims differ from state to state, with regard to their elements and relief. Therefore the subclasses do not have cohesion.

C. Specific v. General Causation

Plaintiffs contend that, to establish a case for medical monitoring, they must establish only that Prempro generally caused an increased risk in the women who took the drug.[128] While Plaintiffs may not have to prove that Prempro caused a specific disease, they must prove that Prempro increased the risk of disease in each particular Plaintiff.

The Third Circuit Court of Appeals addressed this issue:

> [P]laintiffs cannot prove causation by merely showing that smoking cigarettes causes cancer and other diseases. They must demonstrate that defendants' intentional or negligent nicotine manipulation caused each individual plaintiff to have a significantly increased risk of contracting serious latent diseases thereby demonstrating the need for medical monitoring.[129]

---

[127]*Id.* at 208 ("[N]egligence claims depend on individual facts--whether there is a breach of duty or the foreseeability of harm will depend on what Defendants knew or should have known at the time Baycol was prescribed and whether Defendants acted reasonably based on the knowledge it had at that time.").

[128]June 24, 2005 Tr. at 12, lines 33-39.

[129]*Barnes v. American Tobacco Co.*, 161 F.3d at 145.

Although Plaintiffs argue that they need only prove general causation on a class-wide basis, individual causation must still be shown. Because the jury would still have to determine causation for each plaintiff, a finding of "general causation" would not materially advance the litigation.[130] Assuming Plaintiffs could prove that the increased risk of latent disease is generally caused by Prempro, "members of the class seeking to recover for that type of harm would still have to prove individual causation later in the litigation."[131]

The Eleventh Circuit has held:

> Where, after adjudication of the classwide issues, plaintiffs must still introduce a great deal of individualized proof or argue a number of individualized legal points to establish most or all of the elements of their individual claims, such claims are not suitable for class certification . . . ."[132]

This is the case here. "Causation in the air" is not enough.

---

[130]*See Kurczi v. Eli Lilly & Co.*, 160 F.R.D. 667, 677 (N.D. Ohio 1995) ("[T]he resolution of the general causation question accomplishes nothing for any individual plaintiff."); *See also Harding v. Tambrands*, 165 F.R.D. 623, 630 (D. Kan. 1996) ("Certification would not materially advance the disposition of the litigation as a whole. A finding of 'general causation' would do little to advance this litigation."); *Arch v. American Tobacco, Co., Inc.*, 175 F.R.D. at 488 (holding that the plaintiffs could not satisfy the causation elements of products liability and negligence claims by proving that all cigarettes can potentially cause a user to become addicted, because "a jury would still be required to determine for each class member whether he or she is addicted to cigarettes, and, if so, whether defendants (and which defendant) caused the addiction"); *In re Ford Motor Co. Ignition Switch*, 194 F.R.D. at 490 ("It is axiomatic that individual causation remains an prerequisite to class membership. Resolution of the 'general causation' question of whether the subject switches are capable of causing the damage alleged by the vehicle owners does not show commonality under Rule 23(a)(2).").

[131]*Emig v. American Tobacco Co., Inc.*, 184 F.R.D. 379, 390, n.9 (D. Kan. 1998).

[132]*Klay v. Humana, Inc.*, 382 F.3d 1241, 1255 (11th Cir. 2004).

D. The Medical Monitoring Program

Even if Plaintiffs could overcome the lack of cohesion and causation problems, their proposed medical monitoring plan fails to meet key elements generally required by states recognizing medical monitoring relief. For medical monitoring, a plaintiff must establish that a monitoring procedure exists that makes early detection of disease possible, and that this procedure is different from the health monitoring normally recommended in the absence of exposure.[133] Plaintiffs' proposed breast cancer medical monitoring will involve: (1) an initial screening questionnaire; (2) a counseling component to discuss the risks and benefits of Prempro and screening interventions; (3) MRIs in consenting women; and (4) additional studies, such as repeat mammography, echographic studies, or biopsies in women with suspicious lesions on the MRI.[134]

The only part of this proposed program that is different from normally recommended procedures is the MRI. Plaintiffs claim that "Prempro leads to an increase in breast density, thereby making mammograms less accurate than an MRI" in detecting breast cancer.[135] However, Plaintiffs' experts concede that increased breast density caused by Prempro disappears within six months after discontinuation.[136] Since Plaintiffs' proposed subclass includes only women who stopped using Prempro on or before July 2002, no Plaintiff would have the Prempro related increased breast density that Plaintiffs claim requires an MRI. Thus, it cannot be said that

---

[133] *See In re Baycol*, 218 F.R.D. at 211.

[134] Doc. No. 687.

[135] *Id.*

[136] Gale Deposition at 221-222; Jachelson Deposition at 86.

Plaintiffs' proposed monitoring is necessary or different from that which is appropriate for women without increased breast density. Essentially the same problems arise in the proposal for medical monitoring for dementia.

I am impressed by the courts' concerns in *Propulsid* and *Baycol*, where the proposed monitoring programs had not been endorsed by anyone in the medical community, other than the plaintiffs' experts. In denying the certification of a medical monitoring class, the *Propulsid* court noted that:

> [n]either the FDA, nor any medical organization or institution, nor anyone else for that matter, except the plaintiff's expert, has recommended or suggested that a program of medical monitoring for or a group study of all former Propulsid users be undertaken.[137]

This is not to say that a party's expert could never devise an acceptable monitoring program. That expert could be on the leading edge of new medical discoveries and her plan might well be shown to be appropriate. It seems to me, however, that the courts should be mighty chary about outrunning their headlights in the field of medical science. Be that as it may, this is not the case for a court to take lead, based upon the singular opinion of Plaintiffs' experts.

E. No Precedent (Similarities to *Baycol*, *Rezulin*, *Propulsid*, and *Paxil*)

The weight of precedent is against Plaintiffs. First, "no federal Court of Appeals decision has approved class certification of an action involving prescription drugs."[138] In fact, no federal district court has certified a multi-state class alleging products liability and medical monitoring

---

[137] *In re Propulsid*, 208 F.R.D. at 147; *See also In re Baycol*, 218 F.R.D. at 212 (finding that the absence of recommendations from the medical community regarding the need for a medical monitoring program was fatal to the plaintiffs' claims).

[138] *In re Baycol*, 218 F.R.D. at 204.

for a pharmaceutical drug. Since most states that allow medical monitoring require plaintiffs to establish that they were exposed to a "hazardous substance," it is even less likely that a court would grant medical monitoring when the prescription drug at issue is still on the market and approved by the FDA. While these factors are not something that, in and of themselves, defeat Plaintiffs' class certification efforts,[139] I believe they are weighty considerations.

Wyeth relies on what they dub the "big four" -- *In re Baycol*, *In re Rezulin*, *In re Paxil*, and *In re Propulsid* --[140] in opposing Plaintiffs' proposed classes. All four were MDL cases that involved prescription drugs -- class certification was denied in each.[141] And, although Plaintiffs strive to distinguish their case from the "big four," I am not persuaded.

The causes of action and claims for relief in each of the "big four" are almost identical to those in this case. Each of the cases involved consumer fraud and medical monitoring classes, and three of the four sought medical monitoring for asymptomatic plaintiffs.[142] For example, in

---

[139]After all, some case had to be "first" in all new areas of legal involvement.

[140]*In re Baycol*, MDL-1431; *In re Rezulin*, MDL-1348; *In re Propulsid*, MDL-1355; *In re Paxil*, MDL-1574.

[141]*In re Baycol*, 218 F.R.D. 197 (denying class certification of those who ingested the prescription drug Baycol, noting that the claims involved individual issues such as injury, causation, the learned intermediary doctrine, and comparative fault); *In re Rezulin*, 210 F.R.D. 61 (denying motion to certify class of users of a prescription diabetes medication); *In re Paxil*, 212 F.R.D. 539 (denying motion to certify class of users of a prescription antidepressant and anti-anxiety medication); *In re Propulsid*, 208 F.R.D. 133 (denying motion to certify class of users of a prescription heartburn medication).

[142]*In re Rezulin*, 210 F.R.D. at 61 (requesting certification of "a subclass of asymptomatic Rezulin users who have not manifested physical injury"); *In re Baycol*, 218 F.R.D. at 202 ("Plaintiffs seek certification of . . . [a] medical monitoring class consisting of persons who took Baycol and are currently asymptomatic."); *In re Propulsid*, 208 F.R.D. at 133, n.1 (seeking certification of "those claimants who have not suffered a cardiac incident but nevertheless seek equitable relief in the form of the establishment of a clinical study and a medical monitoring

Baycol the plaintiffs asserted claims for strict liability, negligent failure to warn, negligence per se, unjust enrichment, and medical monitoring. The *Baycol* plaintiffs sought: "1. A personal injury class consisting of all persons who claim physical injury caused by Baycol; 2. A medical monitoring class consisting of persons who took Baycol and are currently asymptomatic; and 3. A refund class consisting of all persons who purchased Baycol for personal or family use."[143]

As noted above, Plaintiffs contend that the "big four" can be distinguished.[144] First, Plaintiffs contend that the "big four" cannot serve as precedent here because those cases involved attempts to certify personal injury classes. But the "big four" denied class certification across the board, not just with regard to the personal injury class. The *Rezulin* court held that "[i]ndividual questions would abound even with respect to class members who do not claim to have suffered any physical injury."[145]

Plaintiffs also assert that they are "pursuing, first and foremost, claims for economic loss."[146] However, claims for economic loss were present in the "big four." In each case, the

---

program . . ."); *In re Paxil*, 212 F.R.D. at 542 (requesting certification of a "Rule 23(b)(2) class seeking injunctive relief in the form of medical monitoring").

[143]*In re Baycol*, 218 F.R.D. at 202. *See also In re Rezulin*, 210 F.R.D. at 65 (asserting claims for negligence, fraud, strict products liability, refunds under the New Jersey Consumer Fraud Act, medical monitoring, and unjust enrichment and requesting restitution of revenues and compensatory and punitive damages, as well as the creation of a medical monitoring program); *In re Paxil*, 212 F.R.D. at 542 (seeking "injunctive relief in the form of medical monitoring" and recovery for "violations of unfair competition laws subdivided into three further 'sub-classes' based on differing elements in different states").

[144]*See* June 1, 2005 Tr. at 7, lines 13-16 ("We are going to show the Court that the big four, if it guides this case, is a big mistake. And the reason for it is that every material fact those cases depended upon is distinguishable here.").

[145]*In re Rezulin*, 210 F.R.D. at 67.

[146]June 1, 2005 Tr. at 7, lines 18-19.

plaintiffs sought restitution of monies obtained from the sale of the drug.[147] Each of those courts also rejected the plaintiffs' claims. Regarding the economic claims, the *Rezulin* court held that "[i]ndividual issues would predominate on a restitution claim even in the absence of any claims for compensatory damages."[148]

As stated, when analyzed as a whole, this case is quite similar to the "big four." Without the claims for personal injury, this case and the "big four" are similar in every material way. In fact, some of Plaintiffs' claims are identical to those in the "big four."

F. FRCP 23(a) Requirements

FRCP 23(a), which establishes the prerequisites to a class action, reads:

> One or more members of a class may sue as representative parties on behalf of all only if (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class.[149]

As was mentioned earlier, Plaintiffs have to meet these requirements in addition to at least one of the requirements of the FRCP 23(b) sub parts. Arguably, Plaintiffs have not met these requirements either -- at least not all four of them. However, a full analysis of FRCP 23(a)

---

[147]*In re Baycol*, 218 F.R.D. at 202 (seeking a "refund class consisting of all person who purchased Baycol for personal or family use"); *In re Propulsid*, 208 F.R.D. at 144 (requesting "restitution of all money acquired from the sale of Propulsid"); *In re Paxil*, 212 F.R.D. at 548 (seeking "monetary damages for 'taking the drug when it is no longer needed or wanted' to treat an underlying illness"); *In re Rezulin*, 210 F.R.D at 61(requesting "restitution of the revenues defendants realized from the sale of Rezulin and compensatory and punitive damages").

[148]*In re Rezulin*, 210 F.R.D. at 69.

[149]FED. R. CIV. P. 23(a).

is unnecessary since Plaintiffs failed to meet any of the FRCP 23(b) requirements, which precludes certification.

CONCLUSION

No matter how you cut it, cube it, or slice it, Plaintiffs cannot overcome the problems with individual issues of law and fact, which eclipse any possible common questions or cohesion among their claims. While Plaintiffs have gone to great lengths to fine-tune their class action complaint to avoid suffering from the same problems as those suffered in previous MDL prescription drug class actions, they have failed to chin the pole.

Some judges and courts cast a rather jaundiced eye upon class actions, and use strong language in doing so. See for example, *Matter of Rhone-Poulenc Rorer Inc.*[150] and *In re Bridgestone/Firestone, Inc.*[151] Some writers vigorously challenge this view. As an example Professor Charles Silver of the University of Texas School of Law, takes on the Seventh Circuit judges and even the statements of the sainted Henry Friendly, of the Second Circuit. He disputes their suppositions and factual assertions, and concludes thusly:

> By aggregating hundreds, thousands, or even millions of claims, the class action can make small claims viable and empower claimants in other ways. Defendants dislike class actions for this reason. They prefer single-plaintiff lawsuits in which they possess significant advantages, including economies of scale and superior tolerance for risk. One must therefore expect repeat class action defendants--product manufacturers, financial institutions, insurance companies, directors and officers, etc.--to oppose the use of litigation classes and to enlist the help of tort reform groups and politicians when seeking to defeat them, just as one must expect repeat players on the side of claimants to exert countervailing pressure. The class action will always be a political football.

---

[150] 51 F.3d 1293 (7th Cir. 1995).

[151] 288 F.3d 1012 (7th Cir. 2002).

> It is reasonable to ask judges to keep above the fray and to refrain from fanning the flames unnecessarily. Civil justice processes exist to enforce valid legal rights and obligations, and judges are committed to making these processes more equitable and efficient. Progress toward civil justice, which requires sustained reflection on legal rules and doctrines, economic incentives, and empirical studies, is more likely to be made in a calm environment than in a roiled one.
>
> By describing class actions as legalized blackmail, judges have used inflammatory rhetoric that impugns the character of plaintiffs and trial lawyers who bring class actions, and of trial judges who certify them. They have done this needlessly and, I believe, wrongly. The problem in class actions is not blackmail and does not resemble blackmail in any interesting respect. The problem, assuming it exists, is excessive pressure resulting in decisions to settle made under duress.
>
> When one describes the problem dispassionately, one can see its factual and normative components clearly. One can also see that the argument supporting the claim of duress has not been made persuasively. Some versions of the argument conflict with others. Some versions rest on factual claims that are wrong, doubtful, unproven, or outdated. Some versions conflict with the due process imperative to maximize claim values. Some versions require an account of optimal settlement pressures in lawsuits involving risk-averse parties that has not been set out and that may never be.
>
> Given the sad state of the duress theory, judges hardly are justified in using it at all, let alone in employing incendiary phrases like legalized blackmail. The hard work of thinking the theory through has not been done. Judges should focus on this aspect of the project and leave the task of demonizing plaintiffs, trial lawyers, and trial judges to others.[152]

While it may be neither here nor there, I hold, in general, with those who take a rather kindly view of class actions. They can be the Colt pistol of the little folks, i.e., in appropriate cases, they provide the key to the Temple of Justice for those who could not possibly afford an individual action against an economically advantaged defendant.

Despite all the arguments posited, Plaintiffs failed for the same reasons their predecessors failed: they connot present an adequate class plan or jury instructions; they failed to present a

---

[152]Charles Silver, *"We're Scared to Death": Class Certification and Blackmail*, 78 N.Y.U. L. Rev. 1357, 1429-1430 (2003).

way to manage the laws of the various states in a unitary trial; and individual issues of fact *and* law overwhelmed any common issues.

Plaintiffs' Motion for Class Certification (Doc. No. 80) is DENIED.

IT IS SO ORDERED this 30th day of August, 2005.

/s/ Wm. R.Wilson,Jr.
UNITED STATES DISTRICT JUDGE